REMARKS

Allowable Subject Matter

Applicants acknowledge that Claims 1, 3, 6-18, 23-30, 32, 35-39, 42-44, 57-60 and 63-73 have been found allowable.

Rejection of Claims 47-49, 61, 62, 74 and 75 Under 35 U.S.C. §112, First Paragraph

Claims 47-49, 61, 62, 74 and 75 Under 35 U.S.C. §112, first paragraph, because, according to the Office Action, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims. Particularly, the Office asserted that while the specification enables using the claimed compounds for inhibiting small cell lung cancer cell histone deacetylase and treating small cell lung cancer, the specification does not reasonably enable inhibiting any histone deacetylase and treating any or all cancer implicitly embraced in the claim language. The Office further asserted that an undue amount of experimentation is needed to use the claimed invention commensurate in scope with the claims. For the following reasons, the applicants respectfully traverse.

First, the Applicants note that claims 47-49 and 74 are directed to a method of inhibiting histone deacetylase in a cell. The Office has not alleged that the application does not provide written description support for using the compounds of the invention to inhibit histone deacetylase in a cell, nor that the specification does not enable using the compounds of the invention to inhibit histone deacetylase in a cell. As such claim 47-49 and 74 meet the requirements of 35 U.S.C. § 112.

However, the Office alleges that claims 47-49 and 74 are so-called "reach-through" claims because they "reaches through to inhibiting any or all histone deacetylase and treating any or all cancer in general and thereby they lack adequate written description and enabling disclosure in the specification." The Applicants respectfully disagree. The downstream ramifications of inhibiting histone deacetylase in a cell are not relevant to patentability. The only relevant issues are whether the specification provides written description support and enablement for the method ***as claimed***, *i.e.*, inhibiting histone deacetylase in a cell with the compounds of the invention.

The applicants refer to Trilateral Project B3b, "Mutual understanding in search and examination, Report on Comparative study on biotechnology patent practices, Theme: Comparative study on 'reach-through claims'" issued by the USPTO, EPO, and JPO. In that paper the patent offices address classical "reach-through" claims, which are directed to compounds defined only by function, lacking any structural description, as well as to methods of using such compounds. Such claims are

described as unpatentable because they embrace or require unknown compounds. Claims 47-49 and 74 differ in that the exact identities (*i.e.*, structures) of compounds for use in the method are described in the specification. No case law has been cited, nor are Applicants aware of any case law that supports rejection for lack of written description of claims to the use of structurally defined compounds for a use that is described in the specification. It is up to the Congress and the Federal Courts, through interpretation of Acts of Congress to advance new case law. It is not up to the PTO.

For the foregoing reasons, the Applicants respectfully submit that claims 47-49 and 74 satisfy the written description and enablement requirements and, therefore, requests withdrawal of these rejections. Nevertheless, for completeness, in the following the Applicants address the Office's assertions that claims 47-49 and 74 are not enabled and do not have written description support for methods of treating various cancers and other diseases.

Enablement

As stated above, the Office has not alleged that the claimed invention does not do what it says (i.e., that the application does not provide written description support for using the compounds of the invention to inhibit histone deacetylase in a cell, nor that the specification does not enable using the compounds of the invention to inhibit histone deacetylase in a cell). Therefore, the claimed invention has utility and the specification is enabled for this utility. Of great concern to the Applicants is that the Office is unilaterally determining that the claimed invention lacks a utility that they agree with and is hiding this judgment under the guise of an enablement rejection.

Applicants submit that the specification describes the claimed invention in such terms as to enable a skilled artisan to make and use the full scope of the claimed invention without undue experimentation. A specification is presumed to be enabling, and the burden is on the Office to provide evidence or scientific reasoning to the contrary to support an assertion to the contrary. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

The Office Action directs Applicants attention to Revised Utility and Written Description Guidelines. Applicants appreciate the USPTO guidelines but point out that these guidelines are not controlling with regards to the interpretation of 35 USC and what is or is not enabled. The sole authority for interpreting the laws governing our country and, in particular, the patenting of inventions, falls with the Congress and our Courts, which have consistently held that for enablement the specification need teach only one mode of making and using a claimed composition. see *Cellpro,* 152 F.3d at 1361 (affirming summary judgment of **enablement** of a product claim over a challenge that

two alternative embodiments disclosed in the patent were not enabled because 'the **enablement** requirement is met if the description enables any mode of making and using the invention')." *See Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998); *Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991) . . [T]here is no requirement that the specification enable every mode for making and using the claimed products."; "The reason for such a rule is clear. What would be the value in patenting a composition at all if, by making the slightest alteration in the method of making what is nonetheless the same product, a competitor were able to evade liability? A patent system that permitted such conduct would remove the carrot dangling in front of the inventor's nose. If inventors were so easily divested of their limited monopoly rights attendant to their novel, useful, and nonobvious contributions, they would likely abandon their pursuits and thereby inhibit progress. The law does not permit such an outcome.").

The Office Action is basing the enablement of the claimed invention, not on what is being claimed, but upon a list of possible downstream consequences of what is being claimed. However all of this disregards the teaching of the specification about histone deacetylase (HDAC) inhibitors and methods of inhibiting HDAC with said inhibitors. The downstream consequences of these methods may influence the commercial success of the compounds, however, this does not affect whether or not the methods are enabled for their claimed purpose. Not every **possible** embodiment of a claim need be enabled (See *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1291, 6 USPQ2d 1065, 1073-74 (D. Del. 1987), aff'd 865 F.2d 1247, 9 USPQ2d 1461 (Fed. Cir. 1989) "it is the claimed invention for which enablement is required; A patent applicant is not required ... to predict every possible variation, improvement or commercial embodiment of his invention."). Rather, does the specification teach one skilled in the art to practice the claimed invention (i.e., to inhibit HDAC using the compounds disclosed therein)?

As stated above, Claims 47-49 and 74 are directed towards methods of inhibiting histone deacetylase in a cell by administering the **inhibitors** of histone deacetylase according to Claims 1, 18, 30 and 63, respectively. The compositions of Claims 1, 18, 30 and 63 have been found to be enabled and have been allowed in the instant Office Action. Therefore, methods of using the compositions for their purpose (i.e., using inhibitors of histone deacetylase to inhibit histone deacetylase) are also enabled. Although the claimed compositions may have other uses, Applicants are not required to specifically enable every possible use for the compound and, in fact, need not describe actual embodiments or examples. Indeed, Applicants need not have reduced the invention to practice prior to filing. An enabling *disclosure* is all that is required.

The Office further alleged that Applicants have not provided evidence that the tests in the specification predict using the claimed compounds for treating the various cancers embraced by the claims. In doing so, the Office is reading limitations into the claims that simply are not there. Limitations to therapeutically treating various cancers are simply not present in the rejected claims. Whether or not inhibition of histone deacetylase in a cell, even a specific cancer cell type, results in a therapeutic treatment for such a cell type, such inhibition is still useful. For example, it would be evident to one skilled in the art that inhibition of histone deacetylase in a cancer cell that does not produce a therapeutic effect is a useful tool for probing the role of histone deacetylases in that cancer cell type. Demonstrated inhibition of histone deacetylase (which is clearly measurable as taught in the Specification) without a resultant therapeutic effect would indicate that histone deacetylase is probably **not** involved in the etiology of that cancer cell type. This would be valuable information about the mechanism of progression of that cancer cell type. Of course, if demonstrated inhibition of histone deacetylase activity in a particular cell type **did** correspond to a therapeutic benefit, that would obviously also be useful. Either way, inhibition of histone deacetylase in a cell using the compounds of the claims is a useful invention which is enabled by the specification. The Office has provided no evidence or other reason to doubt that the compounds in claims 47-49 and 74 would inhibit histone deacetylase in any particular cell type, nor that such inhibition would be measurable or would provide useful information.

Since inhibition of histone deacetylase in a cell is a useful invention, whether or not it provides a therapeutic benefit, and since such inhibition of histone deacetylase in a cell is fully enabled by the Specification, Applicants respectfully request that the rejection of claims 47-49 and 74 be withdrawn..

The Office further asserted that because the specification does not sufficiently enable a skilled artisan, undue experimentation is needed to use the claimed compounds for treating cancers. The Office considered factors such as the nature of the invention, state of the prior art, predictability or lack thereof in the art, the amount of guidance, working examples in the specification, breadth of the claims, and quantity of experimentation as further indication that one skilled in the art would have to do undue experimentation. Again, the Office is reading limitations into the claims which do not exist. As discussed above, inhibition of histone deacetylases in any cancer cell type is useful whether or not a therapeutic benefit is achieved. Thus, the enablement question is properly limited to whether the claimed compounds inhibit histone deactylation in various cell types, and whether such inhibition can be ascertained.

With this in mind, Applicants disagree with the Office that undue experimentation is needed. The law clearly states that "a considerable amount of experimentation is permissible, if it is merely routine." *In re Wands,* 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Further, the fact that experimentation may be complex does not necessarily make it undue. *Massachusetts Institute of Technology v. A.B. Fortia,* 774 F.2d 1104 (Fed. Cir. 1985); *In re Wands,* 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Thus, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498 (CCPA 1976).

The claims are directed to inhibiting histone deacetylase in a cell. As discussed above, the specification together with the well-known knowledge in the art provides sufficient guidance to enable skilled artisans to produce the compounds of the invention and use the compounds for inhibiting histone deacetylase in a cell, whether or not the downstream consequence is that such inhibition facilitates treating cancer. The specification describes how to make the compounds and use them for inhibiting histone deacetylase activity. *See* Assay Examples 1-161 of the specification. Any additional experimentation that may be needed is merely routine, using disclosed and well-established and standard synthetic techniques, screening and testing procedures.

With regard to the Wands factors discussed in the Office Action, the foregoing discussion demonstrates that when considering the factors in their totality**,** Claims 47-49, 61, 62, 74 and 75 are enabled. As such, Claims 47-49, 61, 62, 74 and 75 are enabled by the instant specification for their full scope. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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